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Antonio R. Durando  
Durando Birdwell & Janke, P.L.C.  
2929 E. Broadway Blvd.  
Tucson, AZ 85716

[REDACTED] EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
	1753

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/973,388

Applicant(s)

OSIPCHUK, YURI

Examiner

Kaj Olsen

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*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply****A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_\_.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) 14-34 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-13 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.                    6) Other:

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-13, drawn to method of forming high-resistance membrane seal, classified in class 205, subclass 777.5.
  - II. Claims 14-30, drawn to electrophysiological electrode structure, classified in class 204, subclass 403.01.
  - III. Claims 31 and 32, drawn to method of making electrode assembly, classified in class 156, subclass 60.
  - IV. Claims 33 and 34, drawn to method of fabricating partition, classified in class 427, subclass 58.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used without a formed high resistance seal or could form a seal via electrophoresis.
3. Inventions (III or IV) and I are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

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However, because distinction between the product and both the method of using or method of making has either been shown above (or will be shown below), an election of any of groups I, III and IV will **not** result in an examination of the product of group II.

4. Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be constructed without spacers.

5. Inventions IV and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be constructed without etched substrates such as with plastics.

6. Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the partition plate need not be an etched substrate. The subcombination has separate utility such as for an electrophysiological device having a single aperture.

7. During a telephone conversation with Antonio Durando on 5-28-2003 a provisional election was made without traverse to prosecute the invention of group I, claims 1-13.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 specifies a step of reversing the fluid flow though the electrode aperture. This is confusing because the applicant has never specified any step of fluid flow direction earlier in the claim rendering it unclear whether a previous direction of fluid flow is an implied part of the claimed invention. If a previous direction of fluid is not an implied portion of the invention, then it is unclear how to interpret the limitation requiring the fluid to be reversed. Clarification is requested.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 2, 8, 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kostyuk (Nature, vol. 257, pp. 691-693, 1975) in view of Rubinsky et al (USP 6,300,108).

13. Kostyuk discloses a method of forming a high-resistance seal between a biological membrane and an electrode aperture in a partition separating an extracellular compartment (upper fluid compartment of fig. 1) and an intracellular compartment (lower fluid compartment of fig. 1) in a perfusion chamber. Kostyuk discloses a means for delivering extracellular solution into said extracellular compartment and withdrawing the solution via the inflow and outflow respectively shown in fig. 1 (see also p. 693 where the changing of the fluid is discussed). When the biological membrane approaches the electrode aperture, Kostyuk teaches applying a direction of fluid flow through the electrode aperture so as to attract the biological membrane to the electrode structure to form a seal between the biological membrane and the electrode aperture (see first full paragraph on p. 692). With respect to the step of preventing flow of extracellular solution into the intracellular compartment, it would appear the suction provided by the lower compartment is only necessary during whenever a cell needs to be bound to the aperture (or when the intracellular solution needs to be recycled). Hence, if an operator of the device of Kostyuk were pumping the upper compartment to either deliver the cell to the chamber or rinse out the compartment, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to not apply suction from the lower compartment in order to prevent mixing of the fluids in the two compartments and in order to prevent the aperture from undergoing damage caused by unnecessary fluid flow through the aperture. The examiner would contend that in the absence of suction applied to the intracellular compartment, the extracellular solution would be inherently prevented from flowing into the intracellular compartment because

there is no suction being provided by the intracellular compartment, and hence there is no driving force across the aperture. Hence Kostyuk would inherently prevent the claimed step of preventing the flow of extracellular solution from flowing into the intracellular compartment whenever the suction in the intracellular compartment is not applied while fluid flows through the extracellular compartment.

14. Kostyuk does not explicitly recite a step of monitoring the position of the biological membrane in relation to the electrode aperture, Rubinsky teaches in an alternate device for the formation of a high-resistance seal teaches that the position of the membrane (i.e. cell) with respect to the electrode aperture can be monitored so as to determine precisely when to attempt to establish the high-resistance seal (col. 8, lines 15-38). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Rubinsky for the method of Kostyuk in order to know precisely when to applying the suction for forming the high-resistance seal.

15. With respect to claim 2, the extracellular fluid is directed towards the electrode aperture.

16. With respect to claims 8 and 9, see Rubinsky, col. 8, lines 31-38.

17. With respect to claim 12, see Kostyuk, paragraph bridging pp. 691 and 692.

18. With respect to claim 13, exit aperture is adjacent to the electrode aperture (fig. 1 of Kostyuk) giving the claim language its broadest reasonable interpretation.

19. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kostyuk in view of Rubinsky as applied to claim 1 above, and further in view of Baumann et al (USP 6,368,851).

20. The references set forth all the limitations of the claim but did not explicitly disclosed rupturing the membrane with the suction. Baumann teaches in an alternate membrane measuring device that the membrane of the cell can be ruptured utilizing applied pressure (col. 7, lines 1-25). Rupturing the membrane improves the access resistance for the membrane and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Baumann for the method of Kostyuk and Rubinsky in order to lower the access resistance of the cell.

21. With respect to claim 11, the use of pulsatile suction would read on the mere use of a vacuum that can be turned on and off and Kostyuk and Baumann would clearly desire the ability to turn on and off the suction as necessary.

*Allowable Subject Matter*

22. Claims 3-7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

23. The following is a statement of reasons for the indication of allowable subject matter: With respect to claims 3-5, the prior art does not disclose nor render obvious a method comprising all the limitation of claim 2 and further comprising withdrawing the extracellular solution via an opening facing the electrode. With respect to claims 6 and 7, the prior art does not disclose nor render obvious a method comprising all the limitations of claim 1 and further comprising the step of preventing the flow of extracellular solution utilizing the application of pressure.

***Conclusion***

24. In the background to the invention, applicant refers to international applications PCT/EP00/08895 and PCT/GB00/04887. However, neither of the publications associated with the applications qualify as prior art under 35 U.S.C. 102 and they cannot be relied by the examiner in this or any future office action.

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Klemic and WO 01/25769 A2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.



Kaj K. Olsen  
Patent Examiner  
AU 1753  
July 7, 2003